UNDATED

MEMORANDUM

SUBJECT: The revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Triclopyr; PC CODE 116001.

From: John C. Redden, M.S.
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Thru: Ray Kent, Chief
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Health Effects Division (7509C)
and
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To: Virginia Dietrich and Margaret Rice
Accelerated Reregistration Branch
Special Review and Reregistration Division (7508W)

Please find attached the Human Health Assessment for the Triclopyr Reregistration Eligibility Decision Document (RED). This chapter includes the Toxicology chapter from T. McMahon in TBII (ATTACHMENT I), the Product and Residue Chemistry Assessments from W. Smith in CBII (ATTACHMENT II), the Occupational/Residential Exposure Assessment from C. Lang in OREB (ATTACHMENT III), and the Dietary Risk Analysis from B. Steinwand in SAB (ATTACHMENT IV).

Attachments
cc:
William Smith (CHEMII)
Timothy McMahon (TOXII)
Carol Lang (OREB)

Brian Steinwand (SAB)
Paula Deschamp (RCAB)

SUMMARY

Existing tolerances result in a Theoretical Maximum Residue Contribution (TMRC) which represents 0.81% of the RfD for the U.S. general population. The highest subgroup, Non-Nursing Infants (<1 year old) occupies 2.65% of the RfD.

Since the toxicological endpoint to which exposure is being compared in this analysis is a developmental NOEL (30 mg/kg/day), females (13+ years) is the sub population of particular interest. The high end MOE value of 2500 is above the acceptable level and demonstrates no acute dietary concern.

Even at the highest detect (0.58 ppb from the EPA Pesticides in Ground Water Database) risk is minimal.

EFED has reported that triclopyr and its principle degradate TCP are relatively mobile but not particularly persistent. Because it is not expected to reach high concentrations in ground water and it is minimally toxic, HED has concluded that Triclopyr does not present significant risk when aggregate risk is considered.

It is recommended, based on a review of the incident data, that the avoidance of eye and skin contact should be emphasized in the use of triclopyr.

HED does not believe that homeowner exposure will be significant, for the following reasons: the percent ai in products for homeowner use is less than that for agricultural or industrial use; the areas treated are usually limited in size; all products are intended for outdoor use which is likely to reduce the concentration in the environment by allowing dissipation in the outdoor air; the application methods recommended or commonly used by homeowners are not expected to provide significant exposure. Additionally, no toxicological endpoints of concern have been identified by EPA for dermal exposure to triclopyr, therefore, no exposure assessment is required for this exposure; an inhalation exposure assessment is also not required, as stated in the Toxicology Endpoint Selection Document for triclopyr; and no chronic use pattern is expected for homeowner use of triclopyr products.

At this time, no chronic risk assessment is required for handler exposures to triclopyr, since none of the current handler exposure scenarios are likely to result in chronic exposure.

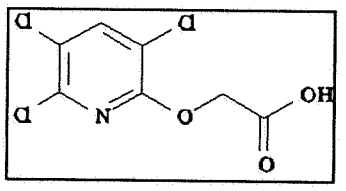
I. SCIENCE ASSESSMENT

A. PHYSICAL AND CHEMICAL PROPERTIES ASSESSMENT

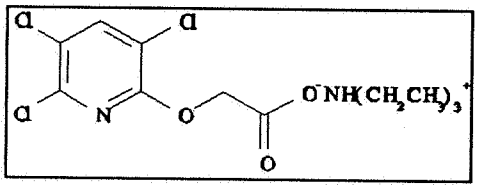
1. Description of Chemical

Triclopyr [((3,5,6-trichloro-2-pyridinyl)oxy)acetic acid] is a systemic herbicide registered for control of woody plants and broadleaf weeds in rice, grass pastures and rangelands, and in rights-of-way, forests, industrial sites, turf, nonirrigation ditchbanks, and homeowner uses. Registered uses are for the triethylamine salt and butoxyethyl ester of triclopyr; there are no registered uses for triclopyr per se, and DowElanco has indicated that this active ingredient will not be supported for reregistration.

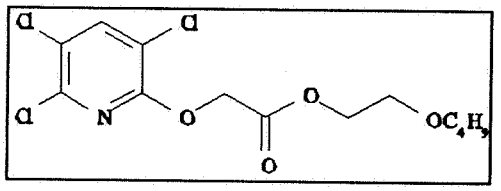
Triclopyr Acid (no active products)
Empirical Formula: $C_7H_4Cl_3NO_3$
Molecular Weight: 256.5
CAS Registry No.: 55335-06-3
Shaughnessy No.: 116001



Triclopyr Triethylamine salt (TEA)
Empirical Formula: $C_{13}H_{19}Cl_3N_2O_3$
Molecular Weight: 371.7
CAS Registry No.: 57213-69-1
Shaughnessy No.: 116002



Triclopyr Butoxyethyl Ester (BEE)
Empirical Formula: $C_{13}H_{16}Cl_3NO_4$
Molecular Weight: 356.6
CAS Registry No.: 64700-56-7
Shaughnessy No.: 116004



2. Identification of Active Ingredient

Triclopyr is a fluffy colorless solid with a melting point of ~148-150 C. Triclopyr TEA is a grayish white granular solid with a melting point of ~111-117 C. Triclopyr TEA is soluble in water at >50% by weight and soluble in methanol at ~65 g/100 mL. Triclopyr TEA is slightly soluble in toluene (~2.7 g/100 mL) and ethyl acetate (~2.1 g/100 mL), and practically insoluble in hexane (<0.02 g/100 mL). Triclopyr BEE is an oil-soluble liquid which is soluble in acetonitrile, methanol, and n-hexane at ≥70% by weight.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 1/4/96 identified two manufacturing-use products (MP) registered to DowElanco under Shaughnessy No. 116002, the 44.4% and 33% triclopyr TEA formulation intermediates (FIs; EPA Reg. Nos. 62719-53 and 62719-232, respectively), and two MPs registered to DowElanco under Shaughnessy No. 116004, the 96% and 61.6% triclopyr BEE FIs (EPA Reg. Nos. 62719-87 and 62719-251, respectively). The registered triclopyr salt and ester MPs and EPs are manufactured by an integrated system from triclopyr BEE.

3. Regulatory Background

The Triclopyr Salts and Esters Phase IV Reviews dated 4/25/91 by J. Smith, determined that DowElanco data submissions for triclopyr TEA (GLNs 61-1, 62-2, and 63-2) and triclopyr BEE (GLNs 61-1, 62-2, 63-2 through 63-4, 63-6, and 63-13) met the acceptance criteria for Phase V review. Additional data were required for the remaining product chemistry data requirements.

The current status of the product chemistry data requirements for the DowElanco triclopyr TEA and BEE TGAIs is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

5. Conclusions

All pertinent data requirements are satisfied for the DowElanco triclopyr BEE TGAI; however, data concerning preliminary analysis (GLN 62-1) of the DowElanco triclopyr TEA TGAI remain outstanding. Provided that DowElanco submits the data required in the attached data summary table for the triclopyr TEA TGAI, and either certifies that the suppliers of beginning materials and the manufacturing processes for the TEA and BEE TGAIs have not changed since the last comprehensive product chemistry review or submits complete updated product chemistry data packages, HED has no objections to the reregistration of triclopyr TEA and BEE with respect to product chemistry data requirements.

B. HUMAN HEALTH ASSESSMENT

1. Hazard Identification

a. Toxicology Data Base

The toxicological data base on Triclopyr is adequate to support reregistration eligibility.

b. Acute Toxicity

Acceptable studies for acute inhalation, primary eye irritation, primary dermal irritation, and dermal sensitization were not available for the technical grade of Triclopyr free acid. However, based on the bioequivalency of the three forms of Triclopyr, acute studies with the TEA or BEE form of Triclopyr are acceptable in place of the free acid. The acceptable acute toxicity studies conducted with Triclopyr indicate low toxicity with the exception of eye irritation, which was conducted with Triclopyr TEA. The Acute Oral LD_{50} in male rats with the free acid form of Triclopyr was 729 mg/kg and 630 mg/kg in female rats, with a Toxicity Category of III (MRID # 00031940). The same toxicity categories were obtained from testing of the TEA and BEE forms of Triclopyr (except eye irritation). The Acute Dermal LD_{50} in rabbits using either the free acid, TEA, or BEE form of Triclopyr was > 2000 mg/kg (Toxicity Category III; MRID #'s 00056009 [free acid], 41443302 [TEA], and 40557005 [BEE]). The Acute Inhalation LC_{50} in male and female rats was > 2.6 mg/L using the TEA form, and >4.8 mg/L using the BEE form with a Toxicity Category of III (MRID #'s 41443303 [TEA] and 40557006 [BEE]). In a primary eye irritation study in rabbits (MRID # 41443304) Triclopyr TEA was found to be corrosive, with corneal involvement present through day 21 post-dose. Using the BEE form, only minimal eye irritation was observed (MRID # 40557007). Both Triclopyr TEA and Triclopyr BEE were found to be non-irritating to the skin of white rabbits (MRID #'s 41443305 [TEA] and 40557008 [BEE]). In dermal sensitization studies in guinea pigs (MRID #'s 41443306 [TEA] and 40557009 [BEE]), sensitization was observed with both forms of Triclopyr. It is noted that acute toxicity studies conducted with Triclopyr BEE (MRID #'s 40557004 through 40557009) showed the same results as those for Triclopyr TEA, with the exception of the primary eye irritation, in which only minimal eye irritation was observed with Triclopyr BEE.

i. Triclopyr acid technical grade

Guideline No.	Study Type	Test Material	Results	Toxicity Category
81-1	Acute Oral	Triclopyr tech.	LD_{50} = 729 mg/kg (M); 630 mg/kg (F)	III
81-2	Acute Dermal	Triclopyr tech.	LD_{50} >2000 mg/kg	III
81-3	Acute Inhalation	Triclopyr acid TGAI study not available		
81-4	Primary Eye Irritation	Triclopyr acid TGAI study not available		
81-5	Primary Dermal Irritation	Triclopyr acid TGAI study not available		
81-6	Dermal Sensitization	Triclopyr acid TGAI study not available		

ii. Triclopyr triethylamine salt (TEA, 44.4% a.i.)

Guideline No.	Study Type	Test Material	Results	Toxicity Category
81-1	Acute Oral	Triclopyr TEA	LD_{50} = 1847 mg/kg (M+F)	III
81-2	Acute Dermal	Triclopyr TEA	LD_{50} >2000 mg/kg	III
81-3	Acute Inhalation	Triclopyr TEA	LC_{50} >2.6 mg/L	III
81-4	Primary Eye Irritation	Triclopyr TEA	Corrosive	I
81-5	Primary Dermal Irritation	Triclopyr TEA	Not irritating	IV
81-6	Dermal Sensitization	Triclopyr TEA	sensitizer	N/A

iii. Triclopyr Butoxyethyl ester, technical grade

Guideline No.	Study Type	Test Material	Results	Toxicity Category
81-1	Acute Oral	Triclopyr BEE,97.1% a.i.	LD_{50} = 803 mg/kg (M+F)	III
81-2	Acute Dermal	Triclopyr BEE, 97.1% a.i.	LD_{50} >2000 mg/kg	III
81-3	Acute Inhalation	Triclopyr BEE, 97.1% a.i.	LC_{50} >4.8 mg/L	III
81-4	Primary Eye Irritation	Triclopyr BEE, 97.1% a.i.	Minimally irritating	III
81-5	Primary Dermal Irritation	Triclopyr BEE, 97.1% a.I.	Not irritating	IV
81-6	Dermal Sensitization	Triclopyr BEE, 97.1% a.i.	sensitizer	N/A

c. Bioequivalency

It is noted that toxicology studies conducted with Triclopyr have been performed using either the free acid, triethylamine salt (Triclopyr TEA), or the butoxyethyl ester (Triclopyr BEE) form of Triclopyr. The issue of bioequivalency of the three chemical forms of Triclopyr (acid, triethylamine salt, and butoxyethyl ester) was addressed by the registrant through conduct of special studies with the triethylamine and butoxyethyl ester forms of Triclopyr. These studies, which included data on comparative disposition, plasma half-life, tissue distribution, hydrolytic cleavage under physiological and environmental conditions for Triclopyr triethylamine salt and Triclopyr butoxyethyl ester (MRID #'s 43394101, 42444701, and 42437901) were found to adequately address the issue of bioequivalency. In addition, subchronic toxicity studies conducted with each form supported the pharmacokinetic data in demonstrating bioequivalence. Therefore, with the exception of the acute toxicity database (where differences in Toxicity Categories have been noted, see above), studies conducted with any one form of Triclopyr can be used to support the Toxicology database as a whole.

d. Subchronic Toxicity

In a subchronic oral toxicity study (MRID # 00150378), male and female Fischer 344 rats received dietary concentrations of Triclopyr technical (98% a.i.) at doses of 0, 5, 20, 50, or 250 mg/kg/day for 13 weeks. Degeneration of the proximal tubules of the kidneys of male and female rats was observed in increased incidence at 20 mg/kg/day and above for both sexes. Absolute and relative kidney weight was significantly increased in male rats at the 50 mg/kg/day dose, while relative kidney weight was increased in male and female rats at 250 mg/kg/day. **The systemic NOEL was 5 mg/kg/day, and the systemic LOEL was 20 mg/kg/day, based on histopathological changes in the kidneys of male and female rats.** This study is **acceptable** and satisfies the guideline requirement [OPPTS 870.3100; OPP §82-1(a)] for a subchronic toxicity study in rodents.

In a 183-day toxicity study in dogs (MRID # 00071794), male and female beagle dogs received dietary doses of triclopyr technical at 0, 0.1, 0.5, or 2.5 mg/kg/day for 183 days (males) or 184 days (females). There were no significant treatment related effects on body weight, food consumption, hematology, or clinical chemistry in male or female dogs. A decreased rate of phenolsulfonthalein (PSP) excretion was observed in dogs receiving 2.5 mg/kg/day Triclopyr. This effect was later determined to be a result of competition between triclopyr and PSP for renal excretion, and was not considered toxicologically relevant (HED document # 008593). **The Systemic NOEL was**

determined to be ≥ 2.5 mg/kg/day, and the Systemic LOEL was determined to be > 2.5 mg/kg/day in both sexes. This study is **supplementary** and does not satisfy the guideline requirement for a subchronic toxicity study [OPPTS 870.3151; OPP §82-1(b)] in non-rodents.

e. Chronic Toxicity and Carcinogenicity

In a 228-day toxicity study in dogs (MRID # 00071793), male and female beagle dogs 14 months of age were administered Triclopyr technical in the diet at doses of 0, 5, 10, or 20 mg/kg/day for 228 days. At the 20 mg/kg/day dose level, body weight gain in male dogs for weeks 0-13 (days 0-95) was decreased 4% below control, and weight gain for the entire study period was decreased 5% below control. For female dogs, body weight gain for weeks 0-13 (days 0-95) was decreased 27% vs control, and was decreased 20% vs control for the entire study period. The decrease in body weight gain for female dogs was matched by a similar decrease in food consumption for both the 0-95 day time period and the 0-228 day time period (21% decrease). Food consumption in male dogs was decreased by 12% for the 0-95 day time period and by 2% for the entire study period. In male and female dogs, hematological parameters at 172 days showed decreased packed cell volume (21% in both sexes), decreased hemoglobin (24% in males, 26% in females), and decreased red cell count (16% in males, 20% in females). These decreases were still observed in both sexes at day ?25 of the study. Elevations in alkaline phosphatase (approximately 2-fold in males and females), SGPT (approximately 2-fold in males, 2-6-fold in females), and SGOT (approximately 2-fold) were observed in male and female dogs at the 20 mg/kg/day dose on days 167, 176, and study termination. Absolute and relative liver weight in male dogs was increased 18% and 26% respectively at the 20 mg/kg/day dose, while relative kidney weight was increased 12% in females at the 20 mg/kg/day dose. Increased incidence of microscopic liver pathology was noted at 20 mg/kg/day in both male and female dogs (focal aggregates of reticuloendothelial cells containing brown pigment surrounded by degenerate appearing hepatocytes; focal areas of eosinophilic granulomatous inflammation).

Based on the decreased body weight gain in male dogs, decreased hematological parameters in male dogs, changes in clinical chemistry in male and female dogs, and liver histopathology in male and female dogs, the **LOEL is 20 mg/kg/day for male and female dogs. The NOEL is 10 mg/kg/day.** This study is classified as **acceptable** and, in conjunction with MRID 41200301 (1-year toxicity study in dogs), satisfies the guideline requirement for a chronic oral toxicity study in dogs [OPPTS 870.4100; OPP §83-1b].

In a one year dietary toxicity study (MRID # 41200301), Triclopyr technical (98.9% a.i.) was administered to male and

female beagle dogs (4/sex/dose) at doses of 0, 0.5, 2.5, or 5.0 mg/kg/day. There were no significant effects of treatment on mortality, clinical signs, body weight, or food consumption in male and female dogs at any dose level tested. Increases in urea nitrogen and creatinine were observed at all dose levels tested. At 12 months, urea nitrogen was increased by 12, 37, and 68% in male dogs and by 11, 17, and 35% in female dogs. Creatinine was increased by 30 and 40% in male dogs at the 2.5 and 5.0 mg/kg/day dose levels, and increased by 55 and 44% in female dogs at 12 months. The changes in clinical chemistry at 2.5 and 5.0 mg/kg/day, while statistically significant, do not represent a toxic response to the test chemical, but a physiologic response of the dog, based on the limited ability of the dog to excrete organic acids at higher plasma concentrations. The lack of histopathologic alterations in the kidneys of both sexes is supportive of this conclusion.

The Systemic NOEL is $\geq$ 5.0 mg/kg/day for both sexes; the Systemic LOEL is > 5.0 mg/kg/day.

This study is classified as supplementary and does not satisfy the guideline requirement for a chronic toxicity study in non-rodents. However, in conjunction with MRID # 00071793, these two studies fulfill the guideline requirement (OPPTS 870.4100; OPP §83-1) for a chronic toxicity study in non-rodents. Therefore, the guideline requirement is satisfied.

In a chronic toxicity/carcinogenicity study, Triclopyr technical (98.0% a.i.) was administered in the diet to groups of male and female ICR mice at dose levels of 0, 50 ppm (**5.55 mg/kg/day** in males, **5.09 mg/kg/day** in females), 250 ppm (**28.6 mg/kg/day** in males, **26.5 mg/kg/day** in females) or 1250 ppm (**143 mg/kg/day** in males, **135 mg/kg/day** in females). Main test groups of 60 mice/sex/dose received diets for 95 weeks, while satellite groups of 40 mice/sex/dose were used for sacrifice of 10 mice/sex/dose at 26 and 52 weeks of treatment at the same dose levels (MRID # 40356601).

At 143 mg/kg/day in males and 135 mg/kg/day in females, body weight gain in male mice was decreased 10.1% vs control for the 22-month study period, while body weight gain in female mice was decreased 10.6% for the 22-month study period. An increase in the incidence of thymic enlargement was observed in high dose male and female mice, but there were no data on thymus weight. At 26 weeks of treatment, plasma BUN in male mice at 143 mg/kg/day was increased 25% vs control, while water consumption was increased an average of 25% at this dose beginning at week 13 of the study. In female mice, kidney weight was increased 10-16% at the 135 mg/kg/day dose, while urinary protein at the 135 mg/kg/day dose was also increased at week 52. However, there were no pathology data to support a true toxic effect on the kidney of males or females. Liver weight in male mice was

increased by 17% at the 143 mg/kg/day dose level at week 26 only.

There were no compound-related tumors observed in male mice. Female mice had a significant increasing trend in mammary gland adenocarcinomas at $p < 0.05$. There were no significant differences in the pair-wise comparisons of the dosed groups with the controls.

For the chronic toxicity portion of this study, the LOEL was tentatively considered to be 143 mg/kg/day in male mice and 135 mg/kg/day in female mice, based on the decreased body weight gain. The NOEL is considered to be 28.6 mg/kg/day in male mice, and 26.5 mg/kg/day in female mice.

Support for the selection of the high dose in the chronic toxicity/ carcinogenicity study is taken from a 28-day range-finding study in which male and female mice were exposed to Triclopyr technical in the diet at dose levels of 0, 200, 400, 800, 1600, or 3200 ppm (nominal doses of 30, 60, 120, 240, and 480 mg/kg/day). At the 480 mg/kg/day dose, male mice were observed with single cell necrosis of the liver, significant increases in alkaline phosphatase, AST, and ALT, and enlargement of the liver with dark color. Centrilobular swelling and degeneration of hepatocytes were observed in a dose-dependent fashion at 120 mg/kg/day and above in male mice, along with mild increases in liver enzymes at 240 mg/kg/day. (MRID # 40356601).

In a chronic toxicity/carcinogenicity study, Triclopyr technical (98.0% a.i.) was administered in the diet to groups of male and female Fischer 344 rats (50/sex/dose) for 2 years at dose levels of 0, 3, 12, or 36 mg/kg/day. Additional groups of 10 rats/sex/dose received dietary exposure to triclopyr at the same dose levels for 6 and 12 months (MRID # 40107701).
Mortality in treated groups of male rats was lower than that in the control group. Cumulative mortality was stated as 50%, 32%, 26%, and 36% for control, low, mid, and high dose level male rats. Red cell count, hemoglobin, and hematocrit in male rats was numerically decreased at the high dose at 6, 12, and 24 months. Statistical significance was achieved for the decrease in red cells at 12 months, for hemoglobin at 6 months, and for hematocrit at 6 and 12 months. Absolute and relative kidney weight was significantly increased (10-17%) at the high dose in male rats, with an apparent dose-related trend at 12 months. Female rats showed an increased incidence of pigmentation of the proximal descending tubule at all dose levels compared to control, while male rats in the 6-month satellite group showed increased incidence of proximal tubule degeneration at the 12 and 36 mg/kg/day dose levels compared to control.

There were no significant increasing **trends** in tumor incidence for male rats. There were significant **pair-wise differences** vs control at 3 and 12 mg/kg triclopyr in the incidence of adrenal

gland benign pheochromocytomas and benign and/or malignant pheochromocytomas combined, and in the incidence of skin fibromas at 3 and 12 mg/kg, with $p < 0.05$ for all comparisons except the incidence of pheochromocytoma (benign + combined) at 12 mg/kg, ($p < 0.01$ vs control).

Female rats had significant increasing trends in mammary gland adenocarcinomas at $p < 0.05$ and in adenomas and/or adenocarcinomas combined at $p < 0.01$. There was a significant difference in the pair-wise comparison of the 36 mg/kg/day dose group with the controls for mammary gland adenomas and/or adenocarcinomas combined at $p < 0.05$. There were no significant pair-wise comparisons or trends for the incidence of adrenal gland pheochromocytoma in female rats (MRID # 40107701).

f. Developmental Toxicity

A developmental toxicity study was conducted with the butoxyethyl ester (BEE) form of Triclopyr in rabbits. In this study, (MRID# 432176-01; HED document # 011107), Triclopyr BEE technical (96.9% a.i.) was administered at doses of 0, 10, 30, and 100 mg/kg/day to pregnant New Zealand White rabbits on gestation days 6 through 18 inclusive.

Maternal toxicity was evident at the 100 mg/kg dose level in the form of mortality during test article administration. In addition, cesarean section data showed a decrease in total number of live fetuses, live fetuses/dam, an increase in post-implantation loss ($p < 0.05$), and an increase in total fetal deaths at 100 mg/kg/day. The maternal LEL = 100 mg/kg based on the increase in mortality at this dose. The maternal NOEL = 30 mg/kg.

Developmental toxicity was evident at the 100 mg/kg dose level in the form of a decreased total number of live fetuses, increased total fetal deaths, increased fetal incidence of additional sternebral centers, increased incidence of reduced ossification of the digital bones, and an increase in the percentage of fetuses with 13 ribs. The developmental LOEL = 100 mg/kg, based on the cesarean section observations of decreased total live fetuses and increased total fetal deaths, as well as the observations of increased fetal and/or litter incidence of skeletal anomalies and variants observed at this dose.The developmental NOEL = 30 mg/kg.

A developmental toxicity study was conducted with the triethylamine (TEA) salt of Triclopyr in rats. In this study, (MRID 432176-02; HED document # 011107), Triclopyr TEA technical

(46.5% a.i.) was administered to timed-mated Crl:CD(SD) BR VAF/Plus female rats on gestation days 6 through 15 inclusive. Doses used were 0, 30, 100, or 300 mg/kg, corrected for compound purity.

Maternal toxicity was suggested at the 300 mg/kg dose level from the increased incidence of clinical signs (salivation) and mortality (1 death). Cesarean section data showed no toxicologically significant alterations in any parameter in treated rats vs control. The maternal LOEL = 300 mg/kg based on the increased incidence of salivation and mortality. The maternal NOEL = 100 mg/kg.

Developmental toxicity was evident in this study at the 300 mg/kg dose level, and included decreased mean fetal body weight, increased fetal and litter incidence of skeletal anomalies (reduced ossification of one or more cranial centers and sacrocaudal vertebral arches). and an increase in the number of fetuses with unossified sternebrae. The developmental LOEL = 300 mg/kg based on decreased mean fetal weight, increased fetal and litter incidence of skeletal anomalies, and increased fetal incidence of unossified sternebrae. The developmental NOEL = 100 mg/kg.

A developmental toxicity study was conducted with the TEA salt of Triclopyr in rabbits. In this study, (MRID 432176-03; HED document # 011701), Triclopyr TEA technical (46.5% a.i.) was administered to pregnant New Zealand White rabbits on gestation days 6 through 18 inclusive. Doses used were 0, 10, 30, or 100 mg/kg, corrected for compound purity. Insemination was by natural means.

Maternal toxicity was evident at the 100 mg/kg dose level in the form of increased mortality during test article administration, decreased body weight gain and food efficiency, and increased liver and kidney weights. Based on these observations, The maternal LOEL = 100 mg/kg based on the decreased body weight gain, decreased food efficiency, and increased liver and kidney weight. The maternal NOEL = 30 mg/kg. Developmental toxicity was evident at the 100 mg/kg dose level in the form of reduced number of litters, reduced number of corpora lutea, reduced number of total implants, reduced total live fetuses, increased embryonic deaths and deaths/dam, and increased pre-implantation loss. The developmental LOEL =100 mg/kg based on the decreased number of live implants, decreased live fetuses, and increased embryonic deaths. The developmental NOEL = 30 mg/kg.

g. Reproductive Toxicity

In a two-generation reproductive toxicity study with the acid form of Triclopyr, (MRID # 435457-01; HED document # 011882), male and female Sprague-Dawley rats (30 males/dose; 30 females/dose), received Triclopyr technical (99.4% a.i.) in the diet at nominal doses of 0, 5, 25, or 250 mg/kg/day (P_1 high dose males received 100 mg/kg/day for the first 29 days of the study). The P_1 generation received Triclopyr in the diet for 10 weeks prior to breeding. After 10 weeks, the P_1 animals were mated on a 1:1 ratio . Following weaning of the F_1 litters, 30 males and 30 females from each treatment group were selected as parents for the next generation. Selected F_1^_rats were treated for 12 weeks with technical triclopyr and then bred to produce the F_2 litter.

Significant systemic toxicity was observed at the 250 mg/kg/day dose level in the P_1 and P_2 parental rats, and included decreased body weight and weight gain during pre-mating for males and females, and decreased body weight and weight gain during gestation for P_1 and P_2 females. For the P_1 parental rats at 250 mg/kg/day, decreased mean litter size was observed as was mean pup weight on days 1, 4, and 21 post-partum; an increased incidence of pup deaths was also observed at 250 mg/kg/day. In the P_2 parental generation, decreased number of litters, mean litter size, number of live pups, and pup weight were significantly decreased at 250 mg/kg/day. In the F_1 and F_2 litters, survival at 250 mg/kg/day was significantly decreased vs. control, as was mean litter size and body weight and weight gain.

At the 25 mg/kg/day dose, an increased incidence of degeneration of the proximal tubules of the kidney was observed in the P_1 and P_2 parental rats of both sexes. The increase at 25 mg/kg/day was dose-related.

The Parental Systemic Toxicity NOEL = 5 mg/kg/day (males and females); the Parental Systemic Toxicity LOEL = 25 mg/kg/day, based on increased incidence of proximal tubular degeneration in male and female P1 and P2 rats.

The Reproductive/Systemic Toxicity NOEL = 25 mg/kg/day; the Reproductive / Systemic Toxicity LOEL = 250 mg/kg/day, based on decreased litter size, decreased body weight and weight gain, and decreased survival in the F1 and F2 litters.

h. Mutagenicity

The mutagenic potential of triclopyr has been adequately evaluated in a range of assays in vivo and in vitro. These assays demonstrate triclopyr is non-mutagenic in vivo and in vitro. These studies are summarized below.

In an Ames mutagenicity assay (MRID # 41732202), Triclopyr BEE (98% a.i.)was found to be non-mutagenic in the four tester strains of Salmonella typhimurium (TA98, TA100, TA1535, and TA1537) in the presence or absence of metabolic activation at the concentrations tested (50-5000 μg/plate). In an in vivo micronucleus assay in mice, Triclopyr BEE was not clastogenic in the mouse micronucleus test at the dose levels tested (0, 60, 200, or 600 mg/kg) [EPA MRID # 41747101]. In an unscheduled DNA synthesis (UDS) assay in rat hepatocytes, Triclopyr BEE did not cause DNA damage or inducible repair in the rat hepatocyte unscheduled DNA synthesis assay at the concentrations of test article used in this study (1.0-1000 μg/ml) [EPA MRID # 41747102].

The mutagenicity of Triclopyr technical acid was evaluated in a recombination repair system using Rec- assay mutant (H17) and recombination repair deficient mutant (M45) of B. subtilis and was also tested in the reverse mutation assay using Salmonella strains TA 98 and TA 100. Concentrations used in the rec- assay were 20-2000 μg/disk, and 1-5000 μg/plate in the reversion assay.
In the rec- assay, there was no evidence of growth inhibition for the repair competent or repair deficient bacterial strains employed. In the reversion assay, there were no increases in number of revertant colonies in the absence or presence of liver S-9 for the strains of Salmonella employed [EPA MRID # 00038408]. In an Ames assay, the mutagenic potential of Triclopyr technical (98.0% a.i.) was assessed in Salmonella tester strains TA-1535, TA-1537, TA-1538, TA-98, and TA-100 in the absence and presence of metabolic activation (rat liver S-9). Concentrations used were 10, 1000, and 10,000 μg/plate. There were no significant increases in the number of revertant colonies for any of the tester strains employed in this study in the absence or presence of metabolic activation [EPA MRID # 00031939].

In a dominant lethal assay, groups of 30 male mice were maintained on dietary levels of Triclopyr of 0, 3, 15, or 70 mg/kg/day for 9 consecutive weeks. Immediately following treatment, each male was mated to 4 untreated mature virgin females for 7 consecutive days. Two of the 4 females in each group were held for the dominant lethal study. Ten days following the last day of cohabitation, females were sacrificed and uteri examined for live and dead implants. There were no significant

toxic effects observed in treated male mice, and no significant differences in body weights. There were no significant effects on fertility index, average number of implantations, average number of resorptions, average resorption rate, or average litter size in any of the untreated female mice bred to treated males at all dose levels of Triclopyr tested [EPA MRID # 00028996].

In a dominant lethal assay, Triclopyr at doses of 0.7, 7.0, and 70.0 mg/kg, triethylene melamine (positive control) at a dose of 0.3 mg/kg, or negative control (corn oil plus saline) were administered orally to separate groups of 10 male Sprague-Dawley rats. Males were sequentially mated to 2 untreated females per week for 7 weeks. Females were killed at 14±2 days after mating. There was an apparent decrease in mating index during week 1 at the 7 and 70 mg/kg dose levels. A trend towards an increase in average number of resorptions was evident at the 7 and 70 mg/kg dose levels, but statistical significance (by t-test) was apparent only at week 4 at the 7 mg/kg dose, week 5 at the 70 mg/kg dose, and week 7 at the 70 mg/kg dose. Statistical comparison by t-test is not appropriate in this type of experimental design. The proportion of females with one or more dead implantations also appeared increased at the 70 mg/kg dose level over negative control. The ratio of dead implants to total implants was also increased at the 7 and 70 mg/kg dose levels, but the increases were numeric in most of the cases [EPA MRID # 00057087].

In an unscheduled DNA synthesis assay, rat primary hepatocyte cultures were exposed to Triclopyr at concentrations of 5×10^{-3}, 1.56×10^{-3}, 5×10^{-4}, 5×10^{-5}, 1.56×10^{-5}, and 5×10^{-6} M for 18 hours in the presence of 10 μCi/ml ^{3}H-thymidine. Triclopyr failed to induce any increase in net nuclear grain counts at any of the concentrations tested. Hepatocyte toxicity was demonstrated at 5×10^{-3} Triclopyr (OPP 84-2; MRID # 40057702).

In a host-mediated assay, Triclopyr was administered orally at doses of 0, 0.7, 7.0, or 70.0 mg/kg to groups of 10 male ICR random bred mice. In the acute test, the indicator organism (Salmonella TA-1530, Salmonella G-46, and Saccharomyces D-3) was injected i.p. immediately after administration of test material. In subacute tests, the indicator organism was injected 1/2 hour after the last of 5 administrations of test material (5 times at 24 hour intervals). Intraperitoneal fluid was recovered, diluted, and plated for determination of revertants and recombinants. Triclopyr in this study induced no significant increases over negative control in mutant or recombinant frequencies at the dose levels used in this study [EPA MRID # 00057085].

In an in vivo cytogenetics study in rats, Triclopyr was administered to groups of 5 Sprague-Dawley rats as single doses of 0.7, 7.0 , and 70.0 mg/kg, or for 5 days to additional groups of 5 rats at the same dose levels. In the single dose study, rats were sacrificed at 6, 24, and 48 hours after test administration, while in the repeated dose study, rats were sacrificed at 5 days after the last dose. Examination of bone marrow cells for chromosomal aberrations from the acute and subacute groups showed no cells with chromosomal aberrations [EPA MRID # 00057086].

i. Metabolism

Disposition and metabolism of ^{14}C-Triclopyr acid (98.8% a.i.) was investigated in male and female rats at a low oral dose (3 mg/kg), repeated low oral doses (3 mg/kg x 14 days), and a high dose (60 mg/kg) [MRID # 41353001]. Comparison of disposition data in intravenously dosed and orally dosed rats demonstrated that Triclopyr was well absorbed after oral administration. Excretion was relatively rapid at the low dose, with a majority of radioactivity eliminated in the urine by 24 hours. At 60 mg/kg, urinary elimination of ^{14}C-Triclopyr derived radioactivity was decreased in male and female rats from 0-12 hours, due to apparent saturation of renal elimination mechanisms. Fecal elimination of ^{14}C-Triclopyr derived radioactivity was a minor route of excretion, as was elimination via exhaled air. No significant effect was observed on metabolism or disposition of ^{14}C-Triclopyr from repeated low oral dosing in male or female rats.

Residual ^{14}C-Triclopyr derived radioactivity was minimal in all dose groups, but measurable levels of tissue radioactivity were detected in perirenal fat of both sexes and ovaries of female rats which apparently increased with dose. Thus, potential accumulation of ^{14}C-Triclopyr derived radioactivity may occur in these tissues.

Urinary metabolites of ^{14}C-Triclopyr were isolated and identified by HPLC and GC/MS. Unmetabolized parent chemical represented >90% of urinary radioactivity, with the remainder accounted for by the metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP), and possible glucuronide and/or sulfate conjugates of 3,5,6-TCP.

Plasma elimination following intravenous administration of ^{14}C-Triclopyr was consistent with a one-compartment model with an elimination half-life of 3.6hr and zero-order kinetics from 0-12 hours at the 60 mg/kg dose. Kinetic parameters were optimized using SIMUSOLV modeling software. The model showed an apparent

"flip-flop" phenomenon, in which absorption at the 3 mg/kg dose was rate limiting in elimination of ^{14}C-Triclopyr derived radioactivity, but renal excretion was saturated and therefore limiting in elimination of ^{14}C-Triclopyr derived radioactivity at the 60 mg/kg dose.

2. Dose Response Assessment

a. Reference Dose (RfD)

The Reference Dose (RfD) for Triclopyr based upon the 2-generation reproduction toxicity study in rats (83-4, MRID # 43545701) with a NOEL of 5.0 mg/kg/day, the lowest dose tested (RfD Peer Review Report of Triclopyr, January 12, 1995). At the next dose level (25 mg/kg/day), an increased incidence of proximal tubular degeneration of the kidneys was observed in P1 and P2 parental rats in this study. An uncertainty factor of 10 for interspecies differences in response and an uncertainty factor of 10 for intraspecies differences in response was applied. Thus, the RfD for Triclopyr was established at 0.05 mg/kg/day (RfD Peer Review meeting of September 4, 1996).

b. Carcinogenicity Classification

As a result of the August 9, 1995 meeting of the Health Effects Division Carcinogenicity Peer Review Committee, Triclopyr was classified as a Group D chemical (not classifiable as to human carcinogenicity).

c. Other Toxicological Endpoints

The Health Effects Division Toxicology Endpoint Selection Committee considered the available toxicology data for Triclopyr at a meeting held on June 11, 1996. Toxicity endpoints and dose levels of concern were identified for use in risk assessment corresponding to acute dietary exposure, short and intermediate term occupational or residential exposure, and chronic occupational or residential exposure.

i. Dermal Absorption

Percent absorbed: Blood levels and urinary excretion of Triclopyr were monitored in five human volunteers who received 3.7 mg/kg Triclopyr BEE on the forearm for a duration of 8 hours. Dermal absorption from this study was calculated to be 1.65% of the applied dose (Carmichael, N.G. Et al. (1989): Oral and Dermal Pharmacokinetics of Triclopyr in Human Volunteers. Human Toxicol. **8**, 431-437.).

Also, in a rabbit dermal absorption study (Accession # 259680), 1.5% of an applied dose of Triclopyr acid (2 g/kg) was reported to be absorbed through the skin. This study was graded core supplementary.

ii. Acute Dietary

To estimate acute dietary risk, the endpoint selected was developmental toxicity. A dose level of 30 mg/kg/day was identified as the NOEL from a developmental toxicity study in rabbits (MRID # 43217601) administered Triclopyr BEE. This NOEL was selected, based on toxicity noted at the next highest dose of 100 mg/kg in which decreased number of live fetuses, increased total fetal deaths, increased resorptions, increased fetal incidence of additional sternebral centers, increased litter incidence of reduced ossification of digital bones, and increased percentage of fetuses with 13 ribs was reported.

iii. Short and Intermediate Term Occupational and Residential

The Health Effects Division Toxicology Endpoint Selection Committee recommended that risk assessments for **short- and intermediate** term exposure were not required since the NOEL was $\geq$ 1000 mg/kg/day (limit dose) in a 21-day dermal toxicity study in rabbits (MRID # 42212701).

iv. Chronic Occupational and Residential (non-cancer)

For **chronic** (non-cancer) occupational or residential exposure risk assessment, a dose level of 5 mg/kg/day was identified as the NOEL for parental/systemic toxicity in a 2-generation reproduction toxicity study in rats (MRID # 43545701). This NOEL was selected based on the observation of proximal tubular degeneration of the kidneys of P1 and P2 parental rats at the next highest dose of 25 mg/kg/day.

v. Inhalation Exposure (any time period)

In an acute inhalation toxicity study (MRID # 41443303), the acute inhalation LC_{50} was determined to be >2.6 mg/L in male and female rats, with a Toxicity category of III.

3. Dietary Exposure and Risk Assessment/Characterization

a. Dietary Exposure (from Food Sources)

i. GLN 171-3: Directions for Use

A search of EPA's REFS database was conducted on 1/4/96 to identify triclopyr end-use products (EPs) with registered food/feed uses. According to REFS, there are two triclopyr triethylamine salt (TEA) and six triclopyr butoxyethyl ester (BEE) EPs registered to DowElanco under FIFRA Section 3 for use on food/feed crops. There are no active triclopyr Special Local Needs (SLN) registrations with uses on food/feed crops. A list of the triclopyr EPs with food/feed uses is presented below.

EPA Reg. No.	Acceptance Date	Formulation	Product Name
62719-37 [1]	7/94	3 lb ae/gal TEA SC/L	Garlon 3A
62719-215 [2]	1/95	3 lb ae/gal TEA WP/D	Grandstand R
62719-40 [1]	9/95	4 lb ae/gal BEE EC	Garlon 4
62719-70	6/93	4 lb ae/gal BEE EC	Remedy
62719-91	2/94	2 lb ae/gal BEE EC	Exetor
62719-176	7/94	0.75 lb ae/gal BEE RTU	Pathfinder
62719-177	2/94	1 lb ae/gal BEE RTU	Basal
62719-260	9/94	2 lb ae/gal BEE EC	Crossbow

[1] This label specifies uses in rights-of-way, industrial sites, non-crop areas, non-irrigation ditch banks, forests, wildlife openings, including grazed areas on these sites.

[2] This product is registered for application to rice only.

A summary of the registered use patterns of triclopyr on pasture and rangeland grasses, based on the product labels registered to DowElanco, is presented in Table A (see APPENDIX II). Triclopyr formulations are typically applied to pasture and rangeland grasses as a broadcast or directed spray when weeds or woody plants are actively growing (postemergence) using ground or aerial equipment. For additional control of woody plants, triclopyr formulations may be applied as stump treatment, basal bark treatment, or dormant brush treatment. All triclopyr labels with registered uses on pasture and rangeland grasses currently specify lengthy and complex grazing and haying restrictions; the specifics of these restrictions are presented in footnote 1 of

Table A (see APPENDIX II). For the reregistration of triclopyr uses on grasses, HED has reevaluated the available residue field trial data in conjunction with the currently registered use patterns, and reassessed the adequacy and appropriateness of grazing and haying restrictions. Our conclusions are stated below.

Label amendments are required to specify a maximum single application rate of 1 lb ae/A and that only one application may be made per growing season. Otherwise, the available field trial data do not support the existing grass forage tolerance. The current maximum registered single application rate on grasses is 9 lb ae/A; a maximum seasonal rate has not been established (see Table A in APPENDIX II). A discussion of the available field residue data in support of the reassessed tolerances at the maximum allowable rate is presented in "Magnitude of the Residue in Plants" section.

The Agency currently considers feeding restrictions and preharvest intervals (PHIs) to be impractical for forage of pasture and rangeland grasses (Table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, issued 9/95). Grass forage tolerances are set using 0-day posttreatment interval data. However, reasonable PHIs are allowed for the cutting of grass hay. Accordingly, label amendments are required to remove all PHIs for grass forage and to specify a 14-day PHI for grass hay. The recommended preharvest interval for grass hay is based on the reassessed tolerance for this commodity. The established 3-day preslaughter interval must be retained. A restriction against grazing lactating dairy animals until the next growing season, as currently found on triclopyr labels, must be retained. All other grazing restrictions are unacceptable and they should be removed from triclopyr labels.

A tabular summary of the residue chemistry science assessments for reregistration of triclopyr is presented in Table B (see APPENDIX II). The conclusions listed in Table B regarding the reregistration eligibility of triclopyr are based on the use pattern specified above for the basic producer, DowElanco. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels be amended such that they are consistent with the basic producer labels.

ii. GLN 171-4 (a): Plant Metabolism

The qualitative nature of the residue is adequately understood based on two studies with [^{14}C]triclopyr on grasses. The terminal residue of concern in/on grass and rice commodities is triclopyr per se. No significant levels of the metabolites 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine were detected.

iii. GLN 171-4 (b): Animal Metabolism

Adequate goat and poultry metabolism studies are available. The major residue in milk, poultry and eggs is triclopyr per se. No significant levels of 2-methoxy-3,5,6-trichloropyridine were detected in any animal commodities. The metabolite 3,5,6-trichloro-2-pyridinol comprised a significant portion of the residue in meat, meat byproducts and fat but no significant levels were detectable in any other animal commodities.

iv. GLN 171-4 (c) and (d): Residue Analytical Methods - Plants and Animals

Enforcement methods: Adequate methodology is available for the enforcement of tolerances for triclopyr residues of concern in/on grass, rice and animal commodities. Two GC methods (Methods I and II) with electron capture detection (GC/ECD) are available for the determination of triclopyr residues of concern. Method I (Dow Chemical Co. Method ACR 77.4) separately determines residues of triclopyr, 3,5,6-trichloro-2-pyridinol, and 2-methoxy-3,5,6-trichloropyridine and has successfully undergone an Agency method validation using grass commodities. The detection limits of Method I ranged from 0.01 to 1 ppm depending on the compound being analyzed. Method II (Dow Chemical Co. Method ACR 77.2) determines residues of triclopyr per se in milk, cream, and tissues, and has detection limits of 0.05-0.1 ppm. Another GC/ECD method is available for the enforcement of tolerances of 3,5,6-trichloro-2-pyridinol in meat; the method is listed in PAM Volume II as Method V under chlorpyrifos. All of the above PAM II methods use diazomethane as a derivatizing agent and benzene as a solvent. The Phase 4 Review stated that the registrant planned to revise the methods to substitute less hazardous reagents.

Data collection methods: Samples of grass commodities collected in response to reregistration requirements were analyzed using Methods ACR 84.2 for triclopyr and ACR 84.4 for 3,5,6-trichloro-2-pyridinol. These methods differ slightly from the enforcement methods listed in PAM Volume II, involving extraction with sodium hydroxide:water:methanol, but eliminating

the use of diazomethane and benzene. Method ACR 84.2 has undergone successful radiovalidation using grass samples from the plant metabolism study.

Multiresidue methods: The FDA PESTDATA database dated 1/94 (PAM Vol. I, Appendix I) indicates that triclopyr is completely recovered (>80%) using multiresidue method PAM Vol. I Section 402. Data pertaining to multiresidue methods testing of triclopyr and its metabolites through Protocols B, C, D, and E have been submitted and forwarded to FDA.

v. GLN 171-4 (e): Storage Stability

The available storage stability data are adequate for the reregistration of triclopyr uses on grasses and rice. Analytical data used in support of reregistration of triclopyr are supported by available storage stability data.

vi. GLN 171-4 (k): Magnitude of the Residue in Plants

Adequate field trial data were submitted in conjunction with PP#1F03991 to support the reregistration of the use on rice.

For the reregistration of triclopyr uses on grasses, the requirements for magnitude of the residue in plants are fulfilled pending compliance by the registrant in adapting the recommended label amendments and tolerance revisions/proposals.

Adequate field trial data, reflecting postemergence use of the registered 4 lb ae/gal BEE EC and 3 lb ae/gal TEA SC/L formulations of triclopyr, are available from the original grass tolerance petition (PP#1F2508); these data are sufficient to reassess the established tolerances for an application rate of 1 lb ae/A. The existing tolerances of 500 ppm for triclopyr residues of concern in/on grass forage and hay were established based on a maximum allowable rate of 1 lb ae/A. Adequate field trial data are not available in support of application rates higher than 1 lb ae/A.

The available data indicate that the residues of triclopyr in/on grass forage collected immediately (0-day) following a single postemergence application of a representative BEE or TEA triclopyr formulation at 1 lb ae/A are below 500 ppm. For comparison purposes, limited field trial data reflecting application rates up to 9 lb ae/A indicate that the maximum residues of triclopyr in/on grass forage collected immediately (0-day posttreatment) were as high as 3333 ppm. The reassessed

tolerance on grass forage will remain at 500 ppm; however, all labels must be amended to reflect the available data that support this tolerance, i.e., the maximum yearly use rate must be restricted to 1 lb ae/A.

For grass hay, the Agency allows the establishment of reasonable PHIs for the cutting of the hay. The available data indicate that the residues of triclopyr in/on grass hay collected 14 days following a single postemergence application of a representative BEE or TEA triclopyr formulation at 1 lb ae/A will not exceed 200 ppm. The reassessed tolerance for grass hay is 200 ppm based on a 14-day PHI.

A discussion of other appropriate restrictions concerning the use of triclopyr on pasture and rangeland grasses is presented in "Directions for Use" section.

vii. GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed

There are no processed food/feed items associated with triclopyr uses on grasses; therefore, no grass processing data are required. An acceptable rice processing study has been submitted and evaluated in conjunction with a petition (PP#1F03991) for the establishment of triclopyr tolerances for rice and poultry commodities. This study indicates that neither triclopyr nor its TCP and 2-methoxy-3,5,6-trichloropyridine metabolites concentrate in rice processed fractions.

viii. GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The requirements for studies depicting magnitude of the residue in milk, fat, meat, and meat byproducts of livestock animals are fulfilled pending compliance by the registrant in adapting the recommended label amendments and tolerance revisions/proposals. An acceptable poultry feeding study has been submitted and evaluated in conjunction with a petition (PP#1F03991) for the establishment of triclopyr tolerances for rice and poultry commodities.

An acceptable dairy cattle feeding study has been submitted/evaluated in support of the original grass tolerance petition (PP#1F2508); this study was re-summarized in the Triclopyr Salts and Esters Phase 4 Review. The existing tolerances for milk (0.01 ppm), for fat, meat, meat byproducts except liver and kidney (0.05 ppm), and for liver and kidney (0.5

ppm), redefined according to the HED Metabolism Committee Decision of 7/15/96 (Table C), are supported by these data provided the labels are amended to comply with recommendations in this chapter.

ix. GLN 171-4 (f, g, and h): Nature and Magnitude of the Residue in Water, Fish and Irrigated Crops

Triclopyr is presently not registered for direct use on water or for aquatic food and feed crops. However, data are currently under review in connection with PP#1F03935 for the registration of triclopyr on aquatic sites.

x. GLN 171-4 (i): Magnitude of the Residue in Food-Handling Establishments

Triclopyr is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

xi. GLNs 165-1 and 165-2: Confined/Field Rotational Crops

An adequate confined rotational crop study has been submitted to support the triclopyr use on rice, including a rotational crop plant-back restriction of 4 months for all crops other than rice. No further data are required in support of the existing label restriction.

b. Dietary Exposure from Drinking Water

The Environmental Fate and Effects Division has concluded:

"EFED concludes that triclopyr and its principle degradate TCP are relatively mobile but not particularly persistent. The multiple potential degradation pathways (hydrolysis, photodegradation, and aerobic soil metabolism) and its rapid degradation, significantly decrease the potential for triclopyr to reach deeper soil horizons. If triclopyr or its degradates reach deeper soil levels where anaerobic conditions exist, persistence will increase and it is more likely to reach ground water. If the compounds did reach ground water, they are not likely to reach or exceed the estimated HA of 35 ppb **[Note: EFED calculated this number before latest RfD for drinking water. HA likely to be much higher i.e. assessment doesn't change.]** The degradate TCP is probably the most mobile of the compounds and the most likely to reach ground water. Because it is not expected to reach high concentrations in ground water and it is not

toxic, EFED concludes that it not a concern for drinking water. However, EFED continues to recommend a ground water label advisory and to keep the ground water study requirement in reserve.

...Triclopyr is not currently regulated under the Safe Drinking Water Act (SDWA); therefore, a Maximum Contaminant Level (MCL) is not established...Public water supply systems are not required to sample and analyze for triclopyr."

A temporary Allowable Residue Level in Drinking Water (ARLDW) in potable water of 0.5 ppm has been established under PP#6G3306. Petitions for the registration of triclopyr in aquatic areas (PP#1F03935) is currently pending.

The EPA Pesticides in Ground Water Database (EPA 734-12-92-001; 9/92) reports 5 detects of triclopyr out of 379 wells tested in four states. The detects range from 0.006 to 0.58 ppb (µg/L).

c. Dietary Risk Assessment and Characterization

i. Chronic Dietary Risk using (TMRC)

A chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups.

Existing tolerances result in a TMRC which represents 0.81% of the RfD for the U.S. general population. The highest subgroup, Non-Nursing Infants (<1 year old) occupies 2.65% of the RfD.

The chronic analysis for triclopyr is a worse case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with triclopyr. Based on the risk estimates calculated in this analysis, it appears that chronic dietary risk from the uses recommended through reregistration, is not of concern.

ii. Acute Dietary Risk

Since the toxicological endpoint to which exposure is being compared in this analysis is a developmental NOEL (30 mg/kg/day), females (13+ years) is the sub population of particular interest.

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no

effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern. The high end MOE value of 2500 (see below) is above the acceptable level and demonstrates no acute dietary concern.

Pregnant Females (13+ Years):

Where RDV = relative dose value
and X = estimated percentage of population user-days with residue contribution exceeding X times the RDV.
Exposure = RDV x X
= 0.01 x 1.2
High End Exposure = 0.012 mg/kg/day

MOE = NOEL/exposure
= 30.0 mg/kg/day/ 0.012 mg/kg/day
MOE = 2500

iii. Drinking Water Risk (Chronic and Acute)

Even at the highest detect (0.58 ppb from the EPA Pesticides in Ground Water Database) risk is minimal.

Acute NOEL = 30 mg/kg/day; Chronic NOEL = 5 mg/kg/day
Highest Detect = .58 ppb = 5.8×10^{-4} mg/L

For a 10 kg child consuming 1 Liter a day (Chronic):

Percent of RfD = $(5.8 \times 10^{-5}$ mg/kg/day $\div$ 0.05) X 100 = 0.12%

For a 60 kg pregnant female consuming 2 Liters a day (Acute):

$(5.8 \times 10^{-4}$ mg/L X 2 L/day) $\div$ 60 kg = 1.93×10^{-5} mg/kg/day
MOE = 30 mg/kg/day $\div$ 1.93×10^{-5} mg/kg/day = 1,554,000

For a 60 kg pregnant female consuming 2 Liters a day (Chronic):

Percent of RfD = $(1.93 \times 10^{-5}$ mg/kg/day $\div$ 0.05) X 100 = 0.04%

iv. Aggregate Risk

Because of the toxicological characteristics of triclopyr (no dermal endpoint of concern identified at this time), EPA determined that a post-application exposure assessment was not necessary. Residential exposure is considered to be negligible

(no dermal endpoint of concern identified at this time). Therefore, no significant non-occupational exposure is expected.

The water exposure value used the highest detect (0.58 ppb from the EPA Pesticides in Ground Water Database)in the calculation.

13+ pregnant females Dietary + Drinking water
$0.012 + 1.93 \times 10^{-5} = 1.2 \times 10^{-2}$ mg/kg/day
Acute MOE = 30 mg/kg/day ÷ 1.2×10^{-2} mg/kg/day = 2,496

4. Occupational and Residential Exposure and Risk Characterization

i. Summary of Use Patterns and Formulations

Triclopyr is a herbicide used on a wide variety of sites. Triclopyr is formulated as an emulsifiable concentrate (16.5 to 61.6 percent active ingredient), a liquid-ready to use (13.6 to 16.7 percent active ingredient), a soluble concentrate (32.5 percent active ingredient), a granular (0.18 to 0.5 percent active ingredient), and as a manufacturing product/liquid (61.6 to 96 percent active ingredient). Triclopyr is used for bark treatment, broadcast, direct spray, foliar treatment, soil treatment, spot treatment and stump treatment. The following equipment is used to apply triclopyr: fixed-wing aircraft, helicopter, hand held spray wand, hand held sprayer, knapsack sprayer, low volume sprayer, power sprayer, groundboom sprayer, foliar pump sprayer, handgun, and hose-end sprayer.

Triclopyr is applied to the following sites: terrestrial feed crops (e.g., pastures and rangelands); terrestrial non-food sites (e.g., airports/landing fields, industrial areas, nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedge rows, nonagricultural uncultivated areas/soils, recreational areas, and ornamental lawns and turf); terrestrial non-food and outdoor residential (e.g., ornamental lawns and turf); aquatic non-food outdoor (e.g., streams/rivers/channeled water); aquatic non-food industrial (e.g., drainage systems); forestry (e.g., forest plantings, forest tree management/forest pest management, and forest trees); and indoor food (e.g., agricultural/farm structures/buildings and equipment).

Occupational-use products and homeowner use products

At this time, products containing triclopyr are intended for both occupational uses and homeowner uses.

ii. Incident Reports

A review of pesticide poisoning incident data (see attached) was completed on June 26, 1996, by Virginia A. Dobozy, VMD, MPH, of OREB. Numerous databases were searched for incident data for triclopyr (PC Code: 116001), triethylammonium triclopyr (PC Code: 116002), and triclopyr butoxyethyl ester (PC Code: 116004). A literature review on possible human and animal adverse effects after exposure to triclopyr was also conducted, although the available literature on these effects proved to be scant.

In summary, there were a total of 72 incident reports in the Incident Data System for triclopyr (PC Codes 116001, 116002, and 116004); 42 reports involved humans, 20 domestic animals and 10 environmental effects. Skin and eye irritation were reported in approximately 12 humans either handling or exposed by drift to triclopyr alone. These effects are consistent with the known toxicity of the chemical. The majority of the incidents resulted after exposure to multiple pesticides and a causal relationship to triclopyr could not be established. The labeling for triclopyr products contains warnings against contact with eyes and skin.

There were a total of 9 illnesses reported to the California Department of Pesticide Regulation from 1982 through 1983 as a result of exposure to triclopyr alone. Seven were incidents of eye or skin effects.

Triclopyr was Number 49 on the Top 200 Active Ingredients for which the National Pesticide Telecommunications Network (a toll-free information service supported by EPA's Office of Pesticide Programs) received calls from 1982-1991. There were 624 calls reporting 125 incidents; 82 were in humans, 21 in animals and 22 others.

It is recommended, based on a review of the incident data, that the avoidance of eye and skin contact should be emphasized in the use of triclopyr.

iii. Residential Exposure

See section v. Post-Application/Reentry Exposure. HED has determined that there are potential exposures to homeowners during usual use-patterns associated with triclopyr. Based on the use patterns identified in the LUIS report and from review of available labels, some exposure scenarios were identified that may be associated with homeowner exposure. These involve application of triclopyr-containing products by means of :

aerosol cans, pump spray bottles, squeeze bottles, "weed sticks," hose-end sprayers, power sprayers, paint brush, rotary and drop spreaders. It is unlikely that power sprayers will be used by homeowners; this is an application method requiring special equipment more apt to be used by agricultural or commercial applicator.

HED does not believe that homeowner exposure will be significant, for the following reasons: the percent ai in products for homeowner use is less than that for agricultural or industrial use; the areas treated are usually limited in size; all products are intended for outdoor use which is likely to reduce the concentration in the environment by allowing dissipation in the outdoor air; the application methods recommended or commonly used by homeowners are not expected to provide significant exposure. Additionally, no toxicological endpoints of concern have been identified by EPA for dermal exposure to triclopyr, therefore, no exposure assessment is required for this exposure; an inhalation exposure assessment is also not required, as stated in the Toxicology Endpoint Selection Document for triclopyr; and no chronic use pattern is expected for homeowner use of triclopyr products.

iv. Occupational Mixer/Loader/Applicator Exposure

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with triclopyr. Based on the use patterns 12 major exposure scenarios were identified for triclopyr: (1a) mixing/loading liquids for aerial application; (1b) mixing/loading liquids for groundboom and handgun application; (2) aerial application of liquids (fixed-wing); (3) aerial application of liquids (helicopter); (4) groundboom application of liquids; (5) handgun sprayer application of liquids; (6) mixing/loading/applying liquids with a backpack sprayer; (7) mixing/loading/applying liquids with a low pressure handwand; (8) applying liquids with an aerosol can; (9) mixing/loading/applying granulars with a push-type spreader; (10) mixing/loading/applying liquids with a hand pump sprayer; (11) mixing/loading/applying liquid with a hose-end sprayer; and, (12) flagging for liquid aerial applications.

Short-term and intermediate-term dermal and inhalation exposure assessments are not required because there are no toxicological endpoints of concern. At this time, no chronic risk assessment is required for handler exposures to triclopyr, since none of the current handler exposure scenarios is likely to result in chronic exposure.

v. Post-Application/Reentry Exposure

EPA has determined that there are potential exposures to persons entering treated sites after application is complete. These include exposures (1) to persons, including children, in recreational (playground) and residential turfgrass areas (2) to workers and other persons in commercial forests, and (3) to workers and other persons in rights-of-ways and other non-crop areas. Because of the toxicological characteristics of triclopyr (no dermal endpoint of concern identified at this time), EPA determined that a post-application exposure assessment was not necessary.

Restricted-Entry Intervals (REIs) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for the dermal toxicity, eye irritation potential, and skin irritation potential are used in determining the WPS REI. If one or more of the three acute toxicity effects are in the toxicity category I, the REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim REI is established at 12 hours. While interim REIs established for triclopyr-containing products range from 12 to 24 to 48 hours, as noted in PR Notice 93-7, Labeling Revisions Required by the Worker Protection Standard, EPA considers, during the reregistration process, all relevant active ingredient and product-specific information to decide whether there is reason to shorten or lengthen the previously established REI. The REI for triclopyr is further addressed in Appendix III, Section IV of this document.

vi. Data Requirements

No additional data are required at this time (see Occupational and Residential Risk Characterization).

b. Occupational and Residential Risk Characterization

Risk From Handler Exposures

Short-term and Intermediate-term Risk: No short- or intermediate-term risk assessment was required for handler exposures to triclopyr because there are no toxicological endpoints of concern identified at this time.

Chronic Risk: At this time, no chronic risk assessment is required for handler exposures to triclopyr, since none of the current handler exposure scenarios is likely to result in chronic exposure.

Risk From Post-Application Exposures

Short-term and Intermediate-term Risk: No short- or intermediate-term risk assessment was required for post-application exposures to triclopyr because there are no toxicological endpoints of concern identified at this time.

Chronic Risk: At this time, no chronic risk assessment is required for post-application exposures to triclopyr, since none of the current post-application exposure scenarios is likely to result in chronic exposure.

Additional Occupational/Residential Exposure Studies

Handler Studies

Handler exposure studies are not required at this time, since there are no toxicological endpoints of concern identified at this time.

Post-Application Studies

Post-application exposure studies are not required at this time, since there are no toxicological endpoints of concern identified at this time.

See APPENDIX III for the following: (SECTION IV - REGULATORY POSITION AND LABELING RATIONALE); and (RED SECTION V - LABELING REQUIREMENTS)

5. FQPA Considerations

Potential Risks to Infants and Children

Studies cited earlier in this document indicate that Triclopyr is not a developmental toxicant, and an additional uncertainty factor for infants and children is unnecessary. This decision is based on the following data.

Since the developmental and reproductive NOELs were either the same or greater than the maternal or parental, HED has determined that it is unlikely that there is additional risk concern for immature or developing organisms which is not

reflected by the risk assessment utilizing the established reference dose.

The effects noted for the RfD NOEL are parental effects, not developmental.

Reference Dose NOEL	Maternal NOEL	Developmental NOEL
5.0 mg/kg/day based on increased incidence of proximal tubular degeneration of the kidneys in male and female P_1 and P_2 animals.	30 mg/kg/day BEE form of Triclopyr rabbit	30 mg/kg/day BEE form of Triclopyr rabbit
	100 mg/kg/day (triethylamine (TEA) salt of Triclopyr rat) based on the increased incidence of salivation and mortality	100 mg/kg/day (triethylamine (TEA) salt of Triclopyr rat) based on decreased mean fetal weight, increased fetal and litter incidence of skeletal anomalies, and increased fetal incidence of unossified sternebrae
	30 mg/kg/day (TEA salt of Triclopyr rabbit) based on the decreased body weight gain, decreased food efficiency, and increased liver and kidney weight	30 mg/kg/day (TEA salt of Triclopyr rabbit) based on the decreased number of live implants, decreased live fetuses, and increased embryonic deaths

NOTE: All three forms of Triclopyr are considered to be bioequivalent.

Drinking Water Risk

Even at the highest detect (0.58 ppb from the EPA Pesticides in Ground Water Database) risk is minimal.

Acute NOEL = 30 mg/kg/day; Chronic NOEL = 5 mg/kg/day
Highest Detect = .58 ppb = 5.8×10^{-4} mg/L

For a 10 kg child consuming 1 Liter a day (Acute):

$(5.8 \times 10^{-4}$ mg/L X 1 L/day) ÷ 10 kg = 5.8×10^{-5} mg/kg/day
MOE = NOEL/Exposure
= 30 mg/kg/day ÷ 5.8×10^{-5} mg/kg/day
MOE = 520,000

For a 10 kg child consuming 1 Liter a day (Chronic):

Percent of RfD = $(5.8 \times 10^{-5}$ mg/kg/day ÷ 0.05) X 100 = 0.12%

For a 60 kg pregnant female consuming 2 Liters a day (Acute):

$(5.8 \times 10^{-4}$ mg/L X 2 L/day) ÷ 60 kg = 1.93×10^{-5} mg/kg/day
MOE = 30 mg/kg/day ÷ 1.93×10^{-5} mg/kg/day = 1,554,000

For a 60 kg pregnant female consuming 2 Liters a day (Chronic):

Percent of RfD = $(1.93 \times 10^{-5}$ mg/kg/day ÷ 0.05) X 100 = 0.04%

Aggregate Risk

Because of the toxicological characteristics of triclopyr (no dermal endpoint of concern identified at this time), EPA determined that a post-application exposure assessment was not necessary. Residential exposure is considered to be negligible. Therefore, residential exposure was not considered in the aggregate risk calculation.

The water exposure value used the highest detect (0.58 ppb from the EPA Pesticides in Ground Water Database) in the calculation.

13+ pregnant females Dietary + Drinking water
0.012 + 1.93×10^{-5} = 1.2×10^{-2} mg/kg/day
Acute MOE = 30 mg/kg/day ÷ 1.2×10^{-2} mg/kg/day = 2,496

Non-nursing infants Dietary + Drinking water

0.05 mg/kg/day + 5.8×10^{-5} mg/kg/day = 5.0×10^{-2} mg/kg/day
Acute MOE = 5 mg/kg/day ÷ 5.0×10^{-2} mg/kg/day = 100

Determination of Safety for U.S. Population

Based on the current state of knowledge for this chemical,

HED has determined that the RfD approach accurately reflects the exposure of the U.S. population, infants and children to Triclopyr.

Tolerance Reassessment Summary

The Triclopyr Salts and Esters Phase 4 Review (4/25/91, J. Smith) has determined that a clarification of the tolerance expression is warranted to reflect application of the butoxyethyl ester and triethylamine salt of triclopyr. Therefore, the tolerance expression should be revised to "residues of triclopyr ... as a result of the application/use of butoxyethyl ester of triclopyr and triethylamine salt of triclopyr."

The HED Metabolism Committee has concluded (7/15/96) that the residue to be regulated in grass and rice commodities and milk, poultry and eggs is triclopyr per se. The residues to be regulated in meat and meat byproducts are the combined residues of triclopyr and the metabolite 3,5,6-trichloro-2-pyridinol (TCP). A summary of tolerance reassessments, with respect to the reregistration of triclopyr uses on grasses and rice, is presented in Table C.

Tolerances Listed Under 40 CFR §180.417(a):

The tolerances listed in 40 CFR §180.417(a) are expressed in terms of the combined residues of triclopyr and its metabolites 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine. Sufficient field trial data are available, contingent upon compliance by the registrant in adapting the recommended label amendments, to ascertain the adequacy of the established tolerances for the following commodities, **as redefined** according to the HED metabolism committee conclusions of 7/15/96: grasses, forage; and grasses, forage, hay. See Table C for recommendations in revisions to commodity names.

The reassessed tolerances for grass forage and hay are 500 ppm and 200 ppm. These reassessed tolerances are contingent upon compliance by the registrant in adapting the recommended label amendments (i.e., a maximum single application rate of 1 lb ae/A, a maximum of 1 application/season, no PHI/PGI for grass forage except for lactating dairy cattle, and a 14-day PHI for grass hay).

Tolerances Listed Under 40 CFR §180.417(b):

The tolerances listed in 40 CFR §180.417(b) are expressed in

terms of the combined residues of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol.

Based on the recommended changes in feeding/grazing restrictions and application rates to grasses, adequate data are available to ascertain the adequacy of the established tolerances for the following commodities, **as defined** in 40 CFR §180.417(b): meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep; and liver and kidney of cattle, goats, hogs, horses, and sheep. See Table C for recommendations in revisions to commodity names. The tolerance for milk is adequate **as redefined** according to the HED metabolism committee conclusions of 7/15/96, i.e., to be expressed in terms of triclopyr per se.

The established tolerances for rice grain, rice straw, eggs and poultry commodities were recently established (60 FOR 4095, 1/20/95) in conjunction with PP#1F03991. These tolerances are adequate **as redefined** according to the HED metabolism committee conclusions of 7/15/96, i.e., to be expressed in terms of triclopyr per se.

Temporary Tolerances and Pending Tolerance Petitions:

Temporary tolerances have been established for fish and shellfish at 0.2 ppm, and a temporary Allowable Residue Level in Drinking Water (ARLDW) in potable water of 0.5 ppm has been established under PP#6G3306. Petitions for the registration of triclopyr in aquatic areas (PP#1F03935) and apples (PP#2F4104) are currently pending.

D. Codex Harmonization

There are no established or proposed Codex MRLs for triclopyr residues. Therefore, there are no issues of compatibility with respect to U.S. tolerances and Codex MRLs.

Table C. Tolerance Reassessment Summary With Respect To Uses Of Triclopyr On Grasses and Rice.[1]

Commodity, As Defined	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.417(a) [2]:			
Grasses, forage	500	500	Redefine as triclopyr per se. [Grass, forage]
Grasses, forage, hay	500	200	Redefine as triclopyr per se. [Grass, hay]
Tolerances Listed Under 40 CFR §180.417(b) [3]:			
Meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep;	0.05	0.05	
Liver and kidney of cattle, goats, hogs, horses, and sheep	0.5	0.5	
Milk	0.01	0.01	Redefine as triclopyr per se.
Rice, grain	0.3	0.3	Redefine as triclopyr per se.
Rice, straw	10.0	10.0	Redefine as triclopyr per se.
Eggs	0.05	0.05	Redefine as triclopyr per se.

Commodity, As Defined	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
Meat, fat, and meat byproducts (except kidney) of poultry	0.1	0.1	Redefine as triclopyr per se.
Fish	0.2	These temporary tolerances, which expire 3/30/97 and were established in conjunction with a petition (PP#1F03935) for the registration of triclopyr in aquatic areas, are not addressed in this Science Chapter.	
Shellfish	0.2		
Water, potable	0.5		

[1] Tolerance reassessments are contingent upon label amendments recommended in this chapter.
[2] Defined as triclopyr and its metabolites 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine.
[3] Defined as triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol.

APPENDIX I

Case No. 2710
Chemical No. 116002

Case Name: Triclopyr, Salts and Esters
Registrant: DowElanco
Product(s): Triethylamine Salt (TEA) TGAI

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number [b]
61-1	Product Identity and Disclosure of Ingredients	N/A [c]	
61-2	Starting Materials and Manufacturing Process	Y	40557101, 40564901, 42090401
61-3	Discussion of Formation of Impurities	Y	40557101, 40564901, 42090401
62-1	Preliminary Analysis	N [d]	42650401 [e,f], No MRID [g]
62-2	Certification of Ingredient Limits	N/A [c]	
62-3	Analytical Methods to Verify the Certified Limits	N/A [c]	
63-2	Color	Y	42650402 [e]
63-3	Physical State	Y	42650402 [e]
63-4	Odor	Y	42650402 [e]
63-5	Melting Point	Y	42650402 [e]
63-6	Boiling Point	N/A [h]	
63-7	Density, Bulk Density or Specific Gravity	Y	42650402 [e]
63-8	Solubility	Y	40440702, 40473603, 41019703, 42090403, 42443401 [i], 42650402 [e]
63-9	Vapor Pressure	Y	41219104, 42090403

63-10	Dissociation Constant	Y	41219106, 42090403
63-11	Octanol/Water Partition Coefficient	Y	41219101, 42090403
63-12	pH	Y	42650402 [e]
63-13	Stability	Y	42650402 [e], No MRID [g]

[a] Y = Yes; N = No; N/A = Not Applicable.

[b] Underlined citations were reviewed under CBRS No. 9145, D172601, 2/12/92, S. Funk; and all other citations were reviewed as noted.

[c] Requirements concerning product identity and the level of impurities in the TGAI will be fulfilled by the submission of adequate preliminary analysis data. Data concerning certified limits and enforcement analytical methods are not required for this TGAI because it is not registered as an MP.

[d] These data do not fully satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) because five batches of the practical equivalent of the TGAI must be analyzed for impurities present at 0.1% of the active ingredient. The supporting data from a properly prepared and statistically justified CSF would constitute an acceptable preliminary analysis submission.

[e] CBRS No. 11370, D188073, 4/22/93, D. McNeilly.

[f] Re-reviewed in CBRS No. 14436, D207726, 10/31/94, D. Miller.

[g] CBRS No. 13372, D198548, 8/4/94, D. Miller.

[h] Data are not required because the TGAI is a solid at room temperature.

[i] CBRS No. 10505, D182060, 10/2/92, F. Toghrol.

Case No. 2710
Chemical No. 116004

Case Name: Triclopyr, Salts and Esters
Registrant: DowElanco
Product(s): Butoxyethyl Ester (BEE) TGAI

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number [b]
61-1	Product Identity and Disclosure of Ingredients	N/A [c]	
61-2	Starting Materials and Manufacturing Process	Y	40557001, 40557101, 42090417
61-3	Discussion of Formation of Impurities	Y	40557001, 40557101, 42090417
62-1	Preliminary Analysis	Y	**40557002**, 42131802
62-2	Certification of Ingredient Limits	N/A [c]	
62-3	Analytical Methods to Verify the Certified Limits	N/A [c]	
63-2	Color	Y	**40557003**
63-3	Physical State	Y	**40557003**
63-4	Odor	Y	**40557003**
63-5	Melting Point	N/A [d]	
63-6	Boiling Point	Y	**40557003**
63-7	Density, Bulk Density or Specific Gravity	Y	40557003, 42090419
63-8	Solubility	Y	41734303 [e] 41019702 [f] 40473601 [g], 42443402 [g]
63-9	Vapor Pressure	Y	42090420
63-10	Dissociation Constant	N/A [h]	
63-11	Octanol/Water Partition Coefficient	Y	
63-12	pH	N/A [h]	
63-13	Stability	Y	**41633702**

[a] Y = Yes; N = No; N/A = Not Applicable.

[b] **Bolded** citations were evaluated in the Triclopyr Salts and Esters Phase IV Review; underlined citations were reviewed under

CBRS No. 9144, D172602, 2/12/92, S. Funk; and all other citations were reviewed as noted.

[c] Requirements concerning product identity and the level of impurities in the TGAI will be fulfilled by the submission of adequate preliminary analysis data. Data concerning certified limits and enforcement analytical methods are not required for the TGAI because it is not a registered MP.

[d] Data are not required because the TGAI is a liquid at room temperature.

[e] CBRS No. 8167, D167231, 8/11/92, D. McNeilly.

[f] CBRS No. 10154, D179878, 8/11/92, D. McNeilly.

[g] CBRS No. 10506, D182058, 11/13/92, A. Aikens.

[h] Data are not required because the TGAI is an oil-soluble liquid.

APPENDIX II

Table A. Registered Use Patterns Of Triclopyr (Case 2710) On Grasses Grown In Pastures And Rangelands.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (ae)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations [1]
Broadcast or directed spray application Postemergence (when weeds or woody plants are actively growing) Ground or aerial (helicopter only)	3 lb ae/gal TEA [2] SC/L [3] [62719-37]	9 lb/A	NS	NS	Applications may be made as high volume leaf-stem treatments, low volume directed spray applications, or broadcast foliar treatments. Applications may be made in a minimum of 20 gal/A using ground equipment and in a minimum of 10 gal/A using aerial equipment. Application may be made alone or as a tank mix with other herbicides. A 48-hour REI has been established.

Table A (continued).

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (ae)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations [1]
	4 lb ae/gal BEE [2] EC [3] [62719-40]	8 lb/A	NS	NS	Use of this product on plants grown for commercial production (i.e., timber production) or on designated grazing areas is prohibited in AZ. Applications may be made as high volume leaf-stem treatments, low volume directed spray applications, or broadcast foliar treatments. Applications may be made in a minimum of 10 gal/A using ground equipment and in a minimum of 5 gal/A using aerial equipment. Application may be made alone or as a tank mix with other herbicides. A 12-hour REI has been established.

Table A (continued).

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (ae)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations [1]
Broadcast or directed spray application Postemergence (when weeds or woody plants are actively growing) Ground	2 lb ae/gal BEE EC [62719-91]	1.5 lb/A	NS	NS	Applications may be made as high volume leaf-stem treatments, low volume directed spray applications, or broadcast foliar treatments. Applications may be made in a minimum of 20 gal/A using ground equipment. Application may be made alone or as a tank mix with other herbicides. No REI has been established.

Table A (continued).

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (ae)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations [1]
Broadcast or directed spray application Postemergence (when weeds or woody plants are actively growing) Ground or aerial	4 lb ae/gal BEE EC [62719-70]	2 lb/A (broadcast) 3 lb/100 gal (leaf-stem)	NS	NS	Applications may be made as high volume leaf-stem treatments or broadcast foliar treatments. Applications may be made in a minimum of 10 gal/A using ground equipment and in a minimum of 2 gal/A using aerial equipment. The product may be prepared with water or as an oil-water emulsion. Application may be made alone or as a tank mix with other herbicides. "At least three consecutive treatments" are recommended for foliar broadcast treatment of Post Oak and Blackjack Oak regrowth stands. No REI has been established.

Table A (continued).

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (ae)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations [1]
Broadcast or directed spray application Postemergence (when weeds or woody plants are actively growing) Ground or aerial (helicopter only)	2 lb ae/gal BEE EC [62719-260]	2 lb/A	NS	NS	Applications may be made as high volume leaf-stem treatments or broadcast foliar treatments. Applications may be made in a minimum of 10 gal/A using ground equipment and aerial equipment. The product may be prepared with water or as on oil-water emulsion. Pastures are not to be reseeded within 3 weeks of treatment. No REI has been established.
Cut surface or stump treatment Ground equipment	3 lb ae/gal TEA SC/L [3] [62719-37]	NS	NS	NS	Applications may be made undiluted or diluted (1:1; v:v). A 48-hour REI has been established.

Table A (continued).

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (ae)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations [1]
Basal bark and dormant brush treatment Ground equipment	4 lb ae/gal BEE EC [3] [62719-40]	1.5 lb/A	NS	NS	The product may be prepared with water or as an oil-water emulsion. A 12-hour REI has been established.
	2 lb ae/gal BEE EC [62719-91]	1.5 lb/A	NS	NS	The product may be prepared with water or as an oil-water emulsion. No REI has been established.
Basal bark or cut stump treatment Ground	0.75 lb ae/gal BEE RTU [62719-176]	NS	NS	NS	Use of this product on plants grown for commercial production (i.e., timber production) or on designated grazing areas is prohibited in AZ. Applications are made undiluted. No maximum application rate is specified; target plants are to be sprayed until wet. A 12-hour REI has been established.

Table A (continued).

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (ae)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations [1]
BAD 50^R**BAD** ^R**BAD** ^R**BAD** ^R**BAD** 50**BAD**	1 lb ae/gal BEE RTU [62719-177]	1.5 lb/A	NS	NS	Applications are made undiluted. Target plants are to be sprayed until wet. No REI has been established.

Table A (continued).

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (ae)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations [1]
Basal bark, dormant stem, or cut stump treatment Ground equipment	4 lb ae/gal BEE EC [62719-70]	120 lb/100 gal (oil; direct to plant) 8 lb/100 gal (oil; directed)	NS	NS	Applications may be made undiluted or diluted with oil or as an oil-water emulsion. No REI has been established.
	2 lb ae/gal BEE EC [62719-260]	8 lb/100 gal (oil; directed)	NS	NS	Applications may be made undiluted or diluted with oil or as an oil-water emulsion. No REI has been established.

[1] All labels specify the following grazing and haying restrictions: A 14-day PHI/PGI has been established for lactating dairy animals after application of ≤2 lb ae/A to green forage; after application of >2 lb ae/A do not harvest green forage or graze lactating dairy animals until the next growing season. A 14-day PHI has been established for other livestock after application of >2 lb ae/A to 6 lb ae/A to green forage; the grazing restriction does not apply if less than 25% of the grazed area is treated. For lactating dairy animals, do not harvest treated hay until the next growing season. For other livestock, do not harvest hay within 7 days after application of ≤2 lb ae/A, within 14 days after application of >2 lb ae/A to 4 lb ae/A, and until the next growing season after application of >4 lb ae/A. A minimum 3-day preslaughter interval applies to animals grazed during the season following treatment, or fed hay harvested during the season following treatment.

[2] Note: TEA = triethylamine salt of triclopyr and BEE = butoxyethyl ester of triclopyr.

Table A (continued).

[3] This label specifies uses in rights-of-way, industrial sites, non-crop areas, non-irrigation ditch banks, forests, wildlife openings, including grazed areas on these sites.

Table B. Residue Chemistry Science Assessments for Reregistration of Triclopyr.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR] [1]	Must Additional Data Be Submitted [2]?	References [3]
171-3: Directions for Use	N/A = Not Applicable	Yes [4]	See Table A
171-4 (a): Plant Metabolism	N/A	No	**PP#1F2508**, **00072443** [5], **4035667**, 42726701 [6], 43122102 [7]
171-4 (b): Animal Metabolism	N/A	No	**00071805**, **00127280**, **40356606**, 42339002 [8], **92189041** [9]
171-4 (c/d): Residue Analytical Methods			
- Plant commodities	N/A	Yes [10]	**00071802**, **00071803**, 43122102 [7], **92189042** [11], **92189043** [12], **92189055** [11], **92189056** [12]
- Animal commodities	N/A	Yes [10]	**00071810-00071814**, 42775001 [6], 42784301 [6], **92189045-92189049** [13], **92189058-92189062** [13]
171-4 (e): Storage Stability	N/A	No	42630101 [14,15,16]
171-4 (k): Magnitude of the Residue in Plants			

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR] [1]	Must Additional Data Be Submitted [2]?	References [3]
- Grass forage	500 (grasses, forage) [§180.417(a)]	No [17]	**PP#1F2508**, **134173**, 41961001 [18], 42090416 [19], 42090424 [20], **92189053** [21], **92189065** [21]
- Grass hay	500 (grasses, forage, hay) [§180.417(a)]	No [17]	**PP#1F2508**, **134173**, 41961001 [18], 42090416 [19], 42090424 [20], **92189053**, **92189065** [21]
- Rice grain	0.3 (rice, grain) [§180.417(b)]	No [22]	
- Rice straw	10.0 (rice, straw) [§180.417(b)]	No [22]	
171-4 (l): Magnitude of the Residues in Processed Food/Feed			
- Rice hulls, bran, and polished rice	--	No [22]	
171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs			

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR] [1]	Must Additional Data Be Submitted [2]?	References [3]
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.01 (milk); 0.05 (fat, meat, mbyp except liver and kidney); 0.5 (liver and kidney) [180.417(b)]	No [23]	**00071806, 00071808, 92189050** [24], **92189052** [25], **92189063** [24], **92189064** [25]
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	0.05 (eggs); 0.1 (fat, meat, mbyp except kidney) [§180.417(b)]	No [26]	
171-4 (f): Nature and Magnitude of the Residue in Water	N/A	N/A [27]	
171-4 (g): Nature and Magnitude of the Residue in Fish	N/A	N/A [27]	
171-4 (h): Nature and Magnitude of the Residue in Irrigated Crops	N/A	N/A	
171-4 (i): Magnitude of the Residue in Food-Handling Establishments	N/A	N/A	

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR] [1]	Must Additional Data Be Submitted [2]?	References [3]
165-1: Rotational Crops (Confined)	--	No	40356607 & 41219108[28]
165-2: Rotational Crops (Field)	--	No	

1. A revision of the tolerance expression is required to reflect application of the butoxyethyl ester and triethylamine salt of triclopyr.

2. The conclusions and deficiencies outlined in this table pertain to the Residue Chemistry Assessments with respect to the reregistration of triclopyr uses on grasses and rice only.

3. **Bolded** references were evaluated in the Triclopyr Salts and Esters Phase 4 Review, J. Smith, 4/25/91; all other references were reviewed as noted.

4. Label amendments are required to: (i) specify a maximum single application rate of 1 lb ae/A and that only one application may be made per growing season; (ii) remove all preharvest and pregrazing intervals for grass forage except for the existing restriction against grazing lactating dairy cattle until the next growing season and (iii) specify a 14-day PHI for grass hay. The existing pre-slaughter interval of 3 days must be retained on labels.

5. MRID 00127280 (an animal metabolism study) was referenced in the Phase 4 Review; however, the List B Inventory for triclopyr identified MRID 00072443.

6. CBTS Nos. 11721, 11722, 11922 and 11958; DP Barcodes D190272, D191646, and D191851; 9/16/93, G. Otakie.

7. CBTS Nos. 12598, 12599, 13247, 13248, 14053, 14054, 14112, 14122, and 14329; DP Barcodes, D195348, D195349, D199607, D199608, D205555, D205557, D205947, and D207324; 9/29/94; G. Otakie.

8. CBRS No. 9946, DP Barcode D178545, 4/25/94, F. Fort.

9. MRID 92189041 is a summary of MRID 40356606.

10. The registrant must either provide justification for the use of diazomethane and benzene in the enforcement methods or replace them with less hazardous yet suitable solvents. In addition, as previously requested, samples from an existing ruminant metabolism study must undergo radiovalidation using the enforcement method.

11. MRIDs 92189042 and 92189055 are summary and reformat, respectively, of MRID 00071803.

12. MRIDs 92189043 and 92189056 are summary and reformat, respectively, of MRID 00071802.

13. MRIDs 92189045-92189049 and 92189058-92189062 are summaries and reformats, respectively, of MRIDs 0007810-0007814.

14. CBRS No. 11302, DP Barcode D187597, 10/8/93, D. Miller.

15. CBRS No. 14578, DP Barcode D208346, 12/16/94, F. Suhre.

16. CBRS No. 15813, DP Barcode D217000, 7/18/96, W. Smith.

17. The reregistration requirements for magnitude of the residue in grass forage and hay are fulfilled pending compliance by the registrant in adapting the recommended label amendments and tolerance revisions/proposals.

18. CBRS No. 8381, DP Barcode D167368, 11/13/91, L. Cheng.

19. CBRS No. 9145, DP Barcode D172601, 2/12/92, S. Funk.

20. CBRS No. 9144, DP Barcode D172602, 2/12/92, S. Funk.

21. MRIDs 92189053 and 92189065 are summary and reformat, respectively, of MRID 00134173.

22. Registration issues pertaining to triclopyr uses on rice are considered in this Science Chapter in order to provide a complete assessment of the present dietary exposure issues for triclopyr; however, the adequacy of the data for this use has been conducted primarily by CBTS in conjunction with PP#1F03991.

23. The reregistration requirements for magnitude of the residue in milk, fat, meat, and meat byproducts of livestock animals are fulfilled pending compliance by the registrant in adapting the recommended label amendments and tolerance revisions/proposals.

24. MRIDs 92189050 and 92189063 are summary and reformat, respectively, of MRID 00071806.

25. MRIDs 92189052 and 92189064 are summary and reformat, respectively, of MRID 00071808.

26. There are no poultry feed items associated with triclopyr uses on grasses. An acceptable poultry feeding study has been submitted and evaluated in conjunction with a petition (PP#1F03991) for the establishment of triclopyr tolerances for rice and poultry commodities.

27. Data pertaining to proposed aquatic uses of triclopyr are currently under review in the Agency (PP#1F03935), and are not addressed in this Science Chapter.

28. CBRS NO. 16901, DP Barcode D222519, 7/2/96, W. Smith.

(SECTION IV - REGULATORY POSITION AND LABELING RATIONALE)

Occupational and Residential Labeling Rationale/Risk Mitigation

The Worker Protection Standard (WPS)

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

At this time some of the registered uses of triclopyr are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Uses that are outside the scope of the WPS include use:

- on pastures or rangelands,
- or in or around animal premises,
- on plants grown for other than commercial or research purposes, such as residential lawns
- on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit. (However, pesticides used on sod farms ARE covered by the WPS).
- in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other noncrop areas.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc.)

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described

in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.
- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Occupational-Use Products

WPS and NonWPS Uses: EPA has determined that occupational handler exposures and risks generally are the same for WPS and nonWPS uses of triclopyr. Therefore, occupational handler exposures and risks are evaluated jointly. As a result of the reregistration evaluation of the acute and other adverse effects of triclopyr, the Agency has determined that risks to handlers do not warrant the establishment of active-ingredient-based minimum personal protective equipment or engineering-control requirements that would apply to all triclopyr end-use products. Handler PPE requirements for triclopyr are to be based solely on the acute toxicity of individual end-use products.

Homeowner-Use Products

EPA is not establishing minimum (baseline) handler PPE for triclopyr end-use products that are intended primarily for homeowner use, because the Agency has determined that the acute and other adverse effects of triclopyr do not warrant PPE requirements.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Interval: Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REI's) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to shorten or lengthen the previously established REI.

During the reregistration process, EPA determined that the restricted-entry interval for all occupational-use products that contain triclopyr and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) should be 48 hours.. The basis for this decision is that triclopyr is categorized as toxicity category I (severe) for eye irritation potential and also is classified as a skin sensitizer.

Early-Entry PPE: The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval, if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS.

The RED requirements for early-entry personal protective equipment are set in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since triclopyr is classified as category IV for skin irritation potential and III for acute dermal toxicity, and EPA has determined that no regulatory action must be taken due to the acute effects or other adverse effects of triclopyr, the PPE for dermal protection required for early entry is the minimum early-entry PPE permitted under the WPS. Since triclopyr is classified as category I for eye irritation potential, protective eyewear is required.

WPS Double Notification Statement:

"Double" notification is the statement on the labels of some pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The interim WPS "double" notification requirement is imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential.

EPA has determined that double notification is not required for triclopyr end-use products.

Occupational-Use Products (NonWPS Uses)

Since EPA has concerns about post-application exposures to persons after nonWPS occupational uses of triclopyr (classified as toxicity category I for eye irritation potential and is a skin sensitizer), it is establishing entry restrictions for all nonWPS occupational uses of triclopyr end-use products. For specific requirements, refer to Section V of this document.

Homeowner-Use Products

Since EPA has concerns about post-application exposures to persons after homeowner applications of triclopyr (classified as toxicity category I for eye irritation potential and is a skin sensitizer), it is establishing entry restrictions for all homeowner uses of triclopyr end-use products. For specific requirements, refer to Section V of this document.

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing triclopyr. For the specific labeling statements, refer to Section V of this document.

(RED SECTION V - LABELING REQUIREMENTS)

LABELING REQUIREMENTS FOR END-USE PRODUCTS

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain triclopyr, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain triclopyr, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use (WPS and nonWPS) and Products Intended Primarily for Homeowner Use

Minimum (Baseline) PPE/Engineering Control Requirements

EPA is not establishing active-ingredient-based minimum (baseline) PPE or engineering control requirements for triclopyr end-use products.

Determining PPE Requirements for End-use Product Labels

Any necessary PPE for each triclopyr end-use product will be established on the basis of the end-use product's acute toxicity category.

Placement in Labeling

For occupational-use products, the personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

For homeowner-use products, the personal protective equipment requirements, if any, must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

Entry Restrictions

For **sole-active-ingredient** end-use products that contain triclopyr the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain triclopyr the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Products Intended Primarily for Occupational Use

WPS Uses

Restricted-entry interval:

A 48-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all triclopyr end-use products.

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:
-- coveralls,
-- chemical-resistant gloves,
-- shoes plus socks, and
-- protective eyewear.

Placement in labeling:

The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions:

The Agency is establishing the following entry restrictions for nonWPS occupational uses of triclopyr end-use products:

For liquid applications:
"Do not enter or allow others to enter the treated area until sprays have dried."

For dry applications:
"Do not enter or allow others to enter the

treated area until dusts have settled."

Placement in labeling:

If WPS uses are also on label -- Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

If no WPS uses are on the label -- Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Products Intended Primarily for Homeowner Use

Entry restrictions:

The Agency is establishing the following entry restrictions for all homeowner uses of triclopyr end-use products:

For liquid applications:
"Do not allow people or pets to enter the treated area until sprays have dried."

For dry applications:
"Do not allow people or pets to enter the treated area until dusts have settled."

Placement in labeling: Place the appropriate entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing triclopyr that are intended primarily for occupational use.

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the

requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements

1. {Registrants: place the following user-safety requirement on the labeling only if coveralls are required for pesticide handlers on the end-use product label:}

Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

2.{Registrants: PLACE THE FOLLOWING USER-SAFETY REQUIREMENT ON THE LABELING always:}

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Skin Sensitizer Statement

"This product may cause skin sensitization reactions in some people."

Products Intended Primarily for Home Use

Application Restrictions

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

{Registrants: place the following user-safety recommendation on the labeling only if gloves and/or protective eyewear are required for homeowner users:}

- "Users should remove protective clothing and equipment immediately after handling this product. Wash the outside of gloves before removing. Keep and wash protective clothing and equipment separately from other laundry."

Skin Sensitizer Statement

"This product may cause skin sensitization reactions in some people."